# EXHIBIT A

**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**WASHINGTON, D.C. 20549**

# FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the fiscal year ended September 30, 2020.

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the transition period from _____ to _____.

Commission File Number 000-23357

# BIOANALYTICAL SYSTEMS, INC.

(Exact name of the registrant as specified in its charter)

| INDIANA | 35-1345024 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| 2701 KENT AVENUE<br>WEST LAFAYETTE, INDIANA | 47906 |
| (Address of principal executive offices) | (Zip code) |

(765) 463-4527
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbols | Name of exchange on which registered |
|---|---|---|
| Common Shares | BASi | NASDAQ Capital Market |

Securities registered pursuant to section 12(g) of the Act: None

Indicate by checkmark if the registrant is a well-known seasoned issuer, as defined by Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by checkmark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller Reporting Company ☒

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒

Based on the closing price on the NASDAQ Capital Market on March 31, 2020, the aggregate market value of the voting and non-voting common equity held by

non-affiliates of the registrant was $24,989,000. As of December 11, 2020, 11,058,366 of registrant's common shares were outstanding.



**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's Proxy Statement to be delivered to stockholders in connection with the 2021 Annual Meeting of Stockholders have been incorporated by reference into Part III of this report.

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**Government Regulation**

The Company is subject to various federal, state, and local laws and regulations and inspections designed to promote compliance therewith. We strive to conduct our business in compliance with applicable laws and regulations. Violations of these laws and regulations by CROs may result in sanctions, including substantial fines, warning letters that require corrective action (including potential facilities improvement requirements), revocation of approvals, exclusion from future participation in government healthcare programs, criminal prosecution and even the denial of the right to conduct business. The Company holds a range of permits and licenses, related to its activities.

We are subject to extensive regulatory requirements designed to ensure the quality and integrity of our data and products and to government inspections and audits related thereto. These regulations include those promulgated under the Federal Food, Drug and Cosmetic Act, as amended from time to time, and include Good Laboratory Practice ("GLP"), Good Manufacturing Practice ("GMP"), Bioequivalence regulations ("BE") and Good Clinical Practices ("GCP"). These requirements demand rigorous attention to research; development; safety; manufacturing quality control; employee training; detailed documentation; equipment and computer validation; promotion and advertising; careful tracking of changes and routine auditing of compliance. Noncompliance with these standards could result in disqualification of project data collected by the Company, which would substantially impact our ability to meet our obligations to clients, and, in severe cases, discontinuance of selected operations. The products and services we offer to international clients are also subject to foreign regulatory requirements, which vary from country to country. Since our formation, we have been inspected, on a routine basis, by the FDA at each of our locations.

We are subject to federal, state and foreign healthcare and other regulations, including anti-bribery and anti-corruption laws (such as the U.S. Foreign Corrupt Practices Act of 1977), and could face substantial penalties if we fail to comply with such regulations and laws. In particular, the relationships that we, and third parties that market and/or sell our products, have with purchasers of our products, are subject to scrutiny under various state and federal laws, including those referred to collectively as healthcare fraud and abuse laws.

The Company's facilities and operations are subject to various federal, state, and local laws and regulations relating to protection of human health and the environment, including those governing the discharge of pollutants into the environment and the storage, handling, use, treatment, disposal, and recycling of hazardous substances and wastes, as further described below. Such laws include, without limitation, the Clean Air Act, the Clean Water Act, the Toxic Substances Control Act, and the Resource, Conservation, and Recovery Act. As environmental laws and regulations continue to evolve, it is likely the Company will be subject to increasingly stringent environmental standards in the future, particularly under air and water quality laws and standards related to climate change issues. Environmental laws are complex, change frequently and have tended to become increasingly stringent over time.

*Analytical Services*

Laboratories that provide information included in INDs, NDAs and BLAs must conform to regulatory requirements that are designed to ensure the quality and integrity of the testing process. Most of our contract research services are subject to government standards for laboratory practices that are embodied in regulations for GLP, GMP, BE and GCP. The FDA, Environmental Protection Agency and other regulatory authorities require that test results submitted to such authorities be based on studies conducted in accordance with the regulations listed above. These requirements include but are not restricted to the following areas:

- Resources – organization, personnel, facilities and equipment;
- Rules – protocols and written procedures;
- Characterization – test items and test systems;
- Documentation – raw data, final report and archives; and
- Quality assurance unit – formalized internal audit function.

We must also maintain reports for each study for specified periods for auditing by the study sponsor and by the FDA or similar regulatory authorities in other parts of the world. Regulatory monitoring authorities such as the FDA, have indicated an increased emphasis on the management of electronic records generated by computerized systems to ensure data integrity. Noncompliance with these regulations can result in the disqualification of data collected during the preclinical trial.

*Nonclinical Services*

Our animal research facilities are subject to a variety of federal and state laws and regulations, including The Animal Welfare Act and the rules and regulations enforced by the United States Department of Agriculture ("USDA") and the National Institutes of Health ("NIH"). These regulations establish the standards for the humane treatment, care and handling of animals by dealers and research facilities. Our animal research facilities maintain detailed standard operating procedures and other documentation necessary to comply with applicable regulations for the humane treatment of the animals in our custody. If the USDA determines that out equipment, facilities, laboratories or processes do not comply with applicable Animal Welfare Act standards, it may issue an inspection report documenting the deficiencies and setting deadlines for any required corrective actions. For continued noncompliance, the USDA may impose fines, suspend and/or revoke animal research licenses or confiscate research animals. In addition to being licensed by the USDA as a research facility, we are also accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International and have registered assurance with the NIH.

**Our failure to comply with the terms of our current Credit Agreement could result in an event of default that could materially adversely affect our business, financial condition and results of operations.**

If there were an event of default under our Credit Agreement, First Internet Bank could cause all amounts outstanding under that agreement to be due and payable immediately or exercise other available remedies, which may have an adverse impact on our business, financial condition and results of operations. An event of default may occur should our assets or cash flow be insufficient to fully repay borrowings under our Credit Agreement, whether paid in the ordinary course or accelerated, or if we are unable to maintain compliance with relevant obligations thereunder, including financial and other covenants. Various risks and uncertainties, including those arising as a result of COVID-19, may impact our ability to comply with our obligations under the Credit Agreement. For example, based in part on the impact of COVID-19 on the Company's operations and financial performance, First Internet Bank agreed to suspend or modify testing of the Fixed Charge Coverage Ratio and the Cash Flow Leverage Ratio covenants under the Credit Agreement for the June 30, 2020, September 30, 2020 and December 31, 2020 compliance periods. Absent these suspensions and modifications, the Company would not have been in compliance with the covenants for the June 30, 2020 and September 30, 2020 measurement periods and expects that it would not have been in compliance with the covenants for the December 31, 2020 measurement period. The modification on August 13, 2020 also updated the definition of Total Funded Debt to at least temporarily exclude Paycheck Protection Program funding received by the Company in connection with the pandemic. Should the pandemic or other factors continue to negatively impact our business or were the government to determine not to forgive the portion of the PPP loan for which we have sought forgiveness, those developments might cause us to fail to comply with the covenants under our Credit Agreement.

In connection with our acquisitions of the Seventh Wave Laboratories, LLC, Smithers Avanza Laboratories, and Preclinical Research Service businesses and the expansion of our facilities in Evansville, Indiana, we have significantly increased our level of indebtedness, as well as our ability to incur further indebtedness under relevant lines of credit. Our ability to service this indebtedness will depend, in part, on the success of our operations and our ability to generate sufficient cash flow therefrom.

***Risks Related to Regulation***

**Changes in government regulation or in practices relating to the pharmaceutical industry could change the demand for the services we provide.**

Governmental agencies throughout the world, but particularly in the United States, strictly regulate the drug development process. Our business involves helping pharmaceutical and biotechnology companies comply with the regulatory drug approval process. Changes in regulation, such as a relaxation in regulatory requirements or the introduction of simplified drug approval procedures, or an increase in regulatory requirements that we may have difficulty satisfying, or that make our services less competitive, could substantially change the demand for our services. Also, if governments increase efforts to contain drug costs and pharmaceutical and biotechnology company profits from new drugs, our clients may spend less, or slow the pace of increased spending, on research and development.

**Any failure by us to comply with existing regulations could harm our reputation and operating results.**

Any failure on our part to comply with existing regulations could result in the termination of ongoing research or the disqualification of data for submission to regulatory authorities. For example, if we were to fail to properly monitor compliance with study protocols, the data collected could be disqualified. Under such circumstances, we may be contractually required to repeat a study at no further cost to the client, but at substantial cost to us. That development would harm our reputation, our prospects for future work and our operating results. Furthermore, the issuance of a notice from the FDA based on a finding of a material violation by us of good clinical practice, good laboratory practice or good manufacturing practice requirements could materially and adversely affect our business and financial performance.

**Privacy regulations could increase our costs or limit our services.**

U.S. Department of Health and Human Services regulations under the Health Insurance Portability and Accountability Act of 1996 demand compliance with patient privacy and confidentiality requirements. In addition, some state governments are considering more stringent regulations. The General Data Protection Regulation (GDPR), which became effective in May 2018, imposes heightened obligations on businesses that control and manage the personal data of E.U. citizens. These and similar regulations might require us to increase our investment in security or limit the services we offer. We could be found liable if we fail to meet existing or proposed regulations on privacy and security of health information.

***Risks Related to Research and Development***

**Our future success depends on our ability to keep pace with rapid technological changes that could make our services and products less competitive or obsolete.**

The biotechnology, pharmaceutical and medical device industries generally, and contract research services more specifically, are subject to increasingly rapid technological changes. Our competitors or others might develop technologies, services or products that are more effective or commercially attractive than our current or future technologies, services or products, or that render our technologies, services or products less competitive or obsolete. If competitors introduce superior technologies, services or products and we cannot make enhancements to our counterparts to remain competitive, our competitive position, and in turn our business, revenues and financial condition, would be materially and adversely affected. Many of our competitors have superior financial and human resources deployed toward research and development efforts. Our relatively constrained financial and human resources may limit our ability to effectively keep pace with relevant technological changes.